

510(k) Premarket Notification
Detect Cytology Brush II
Cook OB/GYN

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J. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

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Device

Trade Name:	Detect™ Cytology Brush II
Common/Usual Name:	Biopsy Brush, Cell Collector
Proposed Classification Name:	Obstetrical-Gynecologic Specialized Manual Instrument

Predicate Devices:

The Detect™ Cytology Brush II is a disposable gynecologic manual instrument for collecting vaginal and cervical cell samples similar to predicate cell collector brushes in terms of indications for use and technology.

Device Description:

The Detect™ Cytology Brush II is a one-time use device for collecting vaginal and cervical cell samples for cytological evaluation and infection diagnosis. The device is not indicated for endometrial cell sampling or for use on pregnant patients. The materials of construction have undergone biocompatibility testing and met the requirements of the tests. Testing was also conducted to characterize the performance and integrity of the device. Results were comparable to those obtained when similarly testing a predicate device.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing procedures similar to devices currently marketed and distributed by Cook OB/GYN. This device is similar with respect to indications for use and design to predicate devices in terms of section 510(k) substantial equivalency.